UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

DATE

EPA-CASAC-13-XXX

The Honorable Bob Perciasepe
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of the EPA's *Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013)*

Dear Acting Administrator Perciasepe:

The Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel met on February 5 - 6, 2013, to peer review the EPA's *Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013),* hereafter referred to as the PA. The CASAC's consensus responses to the agency's charge questions and the individual review comments from the CASAC Lead Review Panel are enclosed. The CASAC's key points are highlighted below.

Overall, the CASAC concurs with the EPA that the current scientific literature does not support a revision to the Primary Lead (Pb) National Ambient Air Quality Standard (NAAQS) nor the Secondary Pb NAAQS. However, many uncertainties and data gaps existed in the prior Lead Pb NAAQS review. Although the current review incorporates a substantial body of new scientific literature, substantial data gaps and uncertainties remain. Therefore the CASAC recommends that research be performed to address these data gaps and uncertainties for future Pb NAAQS reviews. These research needs are detailed in the CASAC's consensus responses.

The CASAC has additional comments and recommendations on improving the document. With the completion of the recommended revisions outlined below and in the consensus responses, the PA will serve its intended purpose. The need for another CASAC review of the document is not anticipated.

The PA should emphasize that Pb is a unique pollutant in many ways. Unlike other criteria air pollutants, Pb is of concern from a multimedia perspective. Millions of tons of Pb are present in the environment from legacy sources. The distribution of this substantial reservoir of Pb is not known. Thus, the extent of current human exposure from this legacy cannot be reliably estimated.

The PA generally captures the key aspects of the health effects evidence presented in the Integrated Science Assessment, but can be made more concise and clear by providing summary conclusions regarding the health effects evidence at the beginning of the sections. The risk and exposure information from the previous Pb NAAQS review is adequately presented. The CASAC concurs that a new risk and exposure assessment (REA) is not needed due the lack of sufficient new scientific information to warrant revision of the prior REA data and methods.

The application of the evidence-based framework and the use of the health risk and exposure information from the previous Pb NAAQS review seem appropriate and provide a sufficient rationale to support retaining the current primary standard without revision. However, there should be more description in the PA of the data and rationale behind the averaging time and form of the current primary standard. Additionally, research is needed to address uncertainties and data gaps in the evidence-based framework and in the health risk and exposure information for future Pb NAAQS reviews.

The PA concisely presents and summarizes the ecological exposure to, effects of, and risk from Pb and provides an appropriate and sufficient rationale to support retaining the current secondary standard without revision. However, questions remain regarding the relevance of the primary standard's indicator, level, averaging time and form for the secondary standard. The CASAC also notes that the 2006 REA performed for the previous Pb NAAQS review had significant uncertainties and data gaps. Overall, four out of the five REA case studies are judged to be of limited or no value for the review of the secondary standard. For future Pb NAAQS reviews, important areas for additional research to support review of the secondary standard include developing a critical loads approach for U.S. conditions is and a multi-media approach to account for legacy Pb and contributions from different sources.

In addition to offering comments and recommendations on the PA, the CASAC, according to its charter, would like to "advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." Although the decrease in childhood lead poisoning in the United States over the last three decades is a great public health success story, concurrently there is a trend of increased export of Pb production, recycling, and recovery to other nations. Thus, indirectly and as an unintended consequence, U.S. policies on Pb may be contributing to adverse public health impacts in other nations, where millions of children continue to suffer from lead poisoning.

One example is the export of spent lead acid batteries (SLAB) to Mexico. Nearly 90 percent of U.S. lead use is in the manufacture of lead acid batteries, nearly all of which are collected for recycling at the end of battery life. In the four years since the implementation of more stringent Pb NAAQS in 2008, U.S. SLAB exports have doubled compared to the previous four years. As recently detailed in a draft report by the Secretariat of the Commission for Environmental Cooperation (CEC), there are serious deficiencies in U.S. oversight of SLAB exports to multiple countries. The CEC also notes that Mexican secondary lead smelters that are receiving U.S. SLAB exports operate under environmental and occupational health regulations that are markedly less protective of public health than U.S. standards.

The CASAC recognizes and commends the EPA's leadership in addressing this preventable health risk in the United States. However, Pb remains a valuable global commodity and the U.S. is a major consumer. We strongly urge the EPA to carefully consider the recommendations of the CEC report, and to support decisive action that will prevent the success of the Pb NAAQS in the United States from occurring at the expense of adverse public health impacts abroad.

The CASAC appreciates the opportunity to provide advice and looks forward to receiving the EPA's response.

Sincerely,

Dr. H. Christopher Frey, Chair
Clean Air Scientific Advisory Committee

Enclosures

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U.S. Environmental Protection Agency
Clean Air Scientific Advisory Committee
CASAC Lead Review Panel (2010-2013)

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Consensus Responses to Charge Questions on EPA's Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013)

Chapter 1 – Introduction

This chapter provides context for the review, including the background of past reviews, as well as the scope for the current review. This includes discussion of fate and multimedia pathways of ambient air Pb and other nonair sources of Pb in the environment.

Does the Panel find the introductory and background material, including that pertaining to previous reviews of the Pb standard and the scope of the current review to be appropriately characterized and clearly communicated?

Chapter 1 of the Policy Assessment (PA) is reasonably well characterized and for the most part clearly communicated, although there are several improvements that should be made (see below). The CASAC concurs with the EPA that the current scientific evidence does not justify a change to the current Lead (Pb) National Ambient Air Quality Standards (NAAQS), with the caveats stated below.

Chapter 1 should emphasize Pb as a unique pollutant in many ways. Historically, anthropogenic emissions of Pb to the air around the globe exceeded natural emissions by a huge margin, more than any other trace metal. Natural emissions come from unpolluted soil, seaspray, and other natural sources. Removal of Pb from gasoline, paint, solder, and other anthropogenic sources constitutes what is arguably the biggest environmental success story for any pollutant to-date. Unlike other criteria air pollutants, Pb is of concern from a multimedia perspective; human exposure to Pb comes from inhalation of air and also from ingestion of food, water, and dust. In addition, Pb may be the pollutant with the biggest legacy problem: millions of tons of Pb are now present in the environment as a result of discharges from years ago. The distribution of this huge reservoir of Pb is not known, and thus current human exposure from this legacy cannot reliably be estimated. What is known, however, is that human activities have on average substantially elevated the Pb content of soil at numerous locations around the United States, more so than other trace metals processed in large quantities. Although air Pb levels are much lower because of reduced emissions, soil Pb can be expected to remain elevated for many years. These unique aspects of Pb, especially the problem of not knowing the distribution of legacy Pb, should be clearly discussed in the PA.

This chapter concludes that there is no information published in the last five years justifying reconsideration of the current NAAQS. Although that is true, this conclusion should be conveyed with an assessment of the adequacy of the old information. In particular, there were significant unknowns and uncertainties associated with a lack of information five years ago; those unknowns and uncertainties still remain.

There are no statements in the PA that the Integrated Science Assessment (ISA) is limited only to exposures and data sources considered currently relevant to the U.S. population, as opposed to populations outside of the United States. Furthermore, the literature is considered only to assess how new studies relate to conclusions drawn in the past review, and then only to studies in the peer-reviewed literature. This has resulted in an ISA that is more than 70% dedicated to toxicology, health effects, biokinetics, and causal determinations. These are areas that were data rich in the last review, and continue to produce volumes of new peer-reviewed information. In contrast, in areas where the least is known and EPA relies on past findings, uncertainty is becoming greater as the existing information becomes outdated.

As a result, it is inaccurate to indicate that no new information has accrued relevant to the impact of U.S. air Pb policy on exposures, health effects, and health and economic damage outside the United States. It is more accurate to say that the current assessment *excludes* consideration of impacts on populations outside of the United States, and that this is a significant change from previous NAAQS reviews.

There is considerable discussion dedicated to the reduction of Pb in air and other media in the United States over the last four decades. Most of the reduction was achieved through the elimination of tetra-ethyl Pb gasoline additives. Another major component of the reduction was substantial decreases in emissions from primary and secondary smelters, and metals processing industries. In the case of motor vehicle gasoline-related emissions, these ceased and other non-Pb products were substituted in commerce. This resulted in decreased Pb emissions and health and environmental effects in both the United States and globally. Within the United States, Pb continues to be used as an octane boosting fuel additive for very high octane fuels used in general aviation for piston engine aircraft. In the case of Pb production and secondary recovery, however, this production and recovery were exported overseas. There is no mention of the impact of the "avoided emissions" in their new locales.

Thus, overall, there is no reason to change the current airborne Pb standard. However, although airborne Pb is far more limited as a problem within the United States, potential exposure to Pb in other environmental media in the United States is likely to be more significant, and most likely high exposures resulting in serious health effects are occurring in areas in the United States not currently being monitored. Furthermore, U.S. policy may be increasing Pb exposures overseas. These issues should be made clear in the PA.

There are a few areas that need revision for clarity and accuracy. On page ES-1, line 25, the following sentence should be added to the end of the paragraph: "This approach was taken to aid in the decision to retain or revise the current standards." On page 1-13 line 35, it states: "And we recognize that past Pb emissions in many situations were well in excess of the current Pb standard." One cannot compare emissions to an airborne standard. This sentence can be revised to state: "We recognize that past Pb emissions in many situations caused airborne Pb concentrations far in excess of the current Pb standard."

Chapter 2 – Ambient Air Lead

This chapter provides an overview of current information on air Pb emissions and monitoring data, consideration of the current air Pb monitoring requirements and an overview of current information on Pb in nonair media.

To what extent does the Panel agree that the most relevant information on emissions (section 2.1), air quality (section 2.2.2), and Pb concentrations in other media (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

With a few minor exceptions (see specific individual panel member comments), the information on Pb emissions, air quality and concentrations in other media is appropriately characterized and clearly presented. Historical and recent (2008) emissions data are summarized quantitatively in clear charts and tables, with additional detail on the 2008 National Emissions Inventory (NEI) data sources and limitations provided in Appendix 2A. There are also qualitative discussions and an informative Appendix 2B on recent regulatory actions, indicating that current emissions have declined since 2008, with additional reductions pending. However, quantitative estimates of emissions reductions should be presented. To the extent that these or other historical controls of U.S. Pb source categories have shifted Pb emissions to other countries, it would be informative to include discussion of those displaced emissions.

The information on ambient air concentrations is clearly presented (for sites with 1 to 3 years of valid data for 2009 to 2011) in maps, charts and in a detailed appendix (Appendix 2D). More recent measurements from sites (including near airports) initiated since the previous Pb NAAQS review would help inform the current Pb NAAQS review, as well as the separate Section 231 aviation gasoline ("avgas") review.

The "not to be exceeded" 3-month rolling average form of the Pb NAAQS requires further justification. An exceedance of the Pb NAAQS could be determined with as few as 3 months of new data. Therefore, it would be useful if more recent data are summarized in the next Pb PA, without being limited to sites with multiple years of valid data.

The information on Pb concentrations in other media is clearly presented. The sections (2.3.2.1 and 2.3.2.2) on indoor and outdoor dust are highly relevant to exposure assessments and would benefit from some added discussion of how dust Pb concentration, loading, and loading rates are measured. In particular, information relating to the differences in particle sizes in dust samples and ambient air samples would be helpful. More information on changes, if any, over time in the availability of historically deposited soil Pb for resuspension to the air or for direct uptake through ingestion could help clarify the significance of this potentially important source category.

With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

The information on ambient Pb monitoring is appropriately characterized and clearly communicated. It is understood that the high-volume (Hi-Vol) Total Suspended Particulates (TSP) sampler is an imperfect historical artifact, and that there is not time for this review cycle of the Pb NAAQS to develop, fully test, and deploy alternative samplers that would consistently capture particles (less than and) greater than 10 microns with appropriate collection efficiencies and size ranges under varying wind speeds and directions. The draft PA notes that the EPA expects a new, improved sampler to be "available for consideration in a future review."

Toward this goal, discussion is needed regarding the desirable cut size characteristics of, and practical constraints on, an alternative sampler. Information from the ISA could be cited here, such as material currently on page 3-67 of the 3rd external draft of the ISA that may be revised for the final ISA regarding discussion of the desirable cut size.

If an alternative low-volume sampler could be developed with an upper 50% particle cut size in the range of 15 to 20 microns, and without the wind speed and direction biases of the Hi-Vol TSP sampler, it seems likely that such a sampler would typically capture as much (or occasionally more) Pb as the Hi-Vol TSP sampler. The CASAC has previously recommended the development of a new air Pb sampler that collects larger particle sizes, that could improve the quality of sampling in the National Air Toxics Trends Station (NATTS) network, and that could serve as an Federal Reference Method (FRM) or Federal Equivalent Method (FEM) for Pb. Filters collected by this sampler also would be amenable to multi-elemental analyses by lower-cost analytical methods and could be useful for more accurate and precise assessments of other particulate pollutants with significant coarse mode concentrations, including chemical contaminants (like hexavalent chromium, silica, and cadmium) and biological components like pollen, fungi, and endotoxins.

Chapter 3 – Health Effects and Exposure/Risk Information

This chapter discusses key policy relevant aspects of the health effects evidence and exposure/risk information.

To what extent does the information in sections 3.1 (Internal Disposition and Biomarkers of Exposure and Dose), 3.2 (Nature of Effects) and 3.3 (Public Health Implications and At-Risk Populations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?

Chapter 3 of the draft PA generally captures the key aspects of the evidence presented in the ISA; therefore, concerns about content stem from the content of the ISA and not its condensation in the PA.

Recognizing the degree of condensation needed to summarize the ISA in only a few pages, this format presents a great writing challenge, and the writing in the chapter lacks clarity. Wordiness should be reduced to directly and efficiently convey the meaning. For example, sentences such as the following could be shortened and recast in a more active voice: "The results from the various case studies assessed, with consideration of the context in which they were derived (e.g., the extent to which the

range of air-related pathways were simulated, and limitations associated with those simulations), and the multiple sources of uncertainty (see section 3.4.7 below) are also informative to our understanding of air-to-blood ratios." (Please refer to Dr. Canfield's individual comments for details on the sentences in need of streamlining and clarification.)

In addition, there are a few places where legacy text from the previous PA remains, so extraneous words need to be deleted and tenses updated. What needs the most attention is the length and complexity of some sentences.

To what extent is the newly available evidence on air-to-blood ratios appropriately characterized and considered in light of information previously available in past reviews?

The new information on air-to-blood ratios is presented in context of previous information and no change in the estimate is justified at this time.

When revising this section (3.1) it would be helpful to first read the last (summary paragraph) on page 3-14. Those conclusions should be included in the first paragraph of the section and then restated at the end of the section when the reader will be in a position to understand the context.

To what extent is the newly available evidence on concentration-response functions for IQ decrements in young children appropriately characterized and considered in light of information previously available in past reviews?

The newly available evidence is appropriately characterized. Parametric information could be extracted from these data to produce quantitative results for blood Pb subgroups, but the quality of the data would not likely provide a useful basis for altering the conclusions reached from the data available prior to 2008.

EPA has correctly identified the lack of information about effects of Pb at levels in the 0-5 µg/dL range. Studies about effects of Pb at these low levels are a future research need.

With regard to the exposure and risk information, to what extent is the information drawn from the human exposure and health risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the now current standard?

Information from the last review is well-characterized and appropriately interpreted, but the clarity of communication should be improved. Putting the conclusion in the first paragraph of the section was very helpful. The CASAC concurs that a new risk and exposure assessment (REA) is not warranted at this time.

Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?

The limitations and uncertainties in the exposure/risk information are well characterized. Epidemiological data are inherently limited; there is a lack of data on the effects of Pb exposure at the levels that are common today and thus concentration-response (C-R) estimates require extrapolation. Parameter choices for biokinetic models typically require restrictive assumptions. No single air quality scenario is adequate.

There are specific areas of the chapter that should be revised for clarity:

- **Page 3-2, Line 15,** referring to distribution of Pb from bone to blood, includes the sentence: "Changes in Pb exposure circumstances also can influence these exchanges, e.g., substantial reductions in exposure levels contribute to increased release of Pb from the bone into the blood (ISA, section 4.3.5)." This sentence should be revised, as it appears to incorrectly characterize the information in section 4.3.5 of the ISA. A reduction in external Pb exposure does not, from a pharmacodynamic standpoint, induce an increase in the release of Pb from bone. In the context of the paragraph, the intended point could be expressed as follows: "When there are substantial reductions in external Pb exposure, the relative contribution of Pb from bone to the concentration of Pb in blood increases."

- **Page 3-5, line 29 to Page 3-6, line 9:** The italicized sentence in this paragraph, reproduced below, should be revised to improve clarity:

  "The response of adult blood Pb levels to appreciable changes in exposure circumstances is generally slower than that of blood Pb levels in young children. For example, simulations using biokinetic models indicate that blood Pb levels in adults achieve a new quasi-steady state within 75-100 days (approximately 3-4 times the blood elimination half-life) subsequent to abrupt increases in Pb intake (ISA, section 4.3.5.2); similar models indicate a much quicker response of blood Pb levels in children both with regard to abrupt increases and reductions in Pb exposure (ISA, section 4.3.5.1). *The response in young children may reflect their much more labile bone pool associated with the rapid turnover of bone mineral in response to their rapid growth rates (ISA, section 4.3.5*). As a result of these physiological processes in young children, their blood Pb levels tend to more quickly reflect changes in their total body burden (associated with their shorter exposure history), and also can reflect changes in recent exposures (ISA, section 4.3.5)."

  Instead of the italicized sentence above, substitution of a sentence such as the following might enhance clarity: "Because the skeletal compartment of Pb is relatively smaller and subject to more rapid turnover in children compared to adults, the blood Pb concentration of children is more reflective of their recent external exposure."

- **Page 3-19 lines 23-24**: It might be clearer to use the phrase "qualitatively change" rather than "appreciably change" to allow for appreciable strengthening of the previous conclusion but no change of consequence.

- **Page 3-22 lines 17-23:** This is a helpful discussion of the problem with unknown earlier exposures in adults and older children. The topic comes up multiple times throughout this document and becomes redundant. Maybe this should be covered fully (including this as a general critique of cross-sectional studies), early in the chapter and then simply referred back to when the context warrants.

Chapter 4 – Review of the Primary Standard for Lead

This chapter describes the basis for the current primary standard and consideration of the current evidence and exposure/risk-based information with regard to reaching preliminary staff conclusions about the adequacy of the current standard.

In this chapter, staff applies the same evidence-based air-related IQ loss framework as developed and used in the last review, which has fundamentally two key inputs: an air-to-blood ratio and the slope of a concentration-response (C-R) function for IQ decrements in young children.

This draft PA is constrained by the absence of appreciable new observational and experimental data that addresses at least in part, limitations and uncertainties in the evidence that was present at the time of the last update of the Pb NAAQS. Assuming the approach used in the previous PA was appropriate at the time, by default, it is reasonable to extend it now. However, this circumstance underscores a fundamental dilemma. That is, until evidence is available to assess Pb exposure and health risks related to air Pb levels reflecting the current standard, a substantive refinement and update of the PA will not be possible. The obvious uncertainty underlying evaluation of this PA is whether lowering the standard would (or would not) impact exposure and thus risk. The CASAC agrees with the EPA conclusion that "there is appreciable uncertainty associated with drawing conclusions regarding whether there would be reductions in blood Pb levels from alternative lower levels as compared to the level of the current standard." If lowering the primary standard would lower blood Pb levels amongst the U.S. population, then there would be potential public health benefits from a lower standard. Research priorities discussed below are designed to help inform these uncertainties.

To what extent does the Panel agree with application of the evidence-based framework from the last review, particularly with regard to consideration of the currently available information, and related limitations and uncertainties, for air-to-blood ratios and C-R functions for IQ decrements in young children?

The application of the evidence-based framework from the previous Pb NAAQS review seems appropriate. The new literature published since the previous review provides further support for the health effect conclusions presented in that review. Additionally, the new studies do not fundamentally alter the uncertainties for air-to-blood ratios or C-R functions for IQ decrements in young children.

As previously discussed with CASAC, staff concluded that the current information does not warrant development of a new REA in this review. Thus, exposure/risk information was drawn from the REA conducted in the last review.

What are the Panel's views on staff's interpretation of the exposure/risk information, and on staff's conclusions that the information is generally supportive of conclusions drawn from the evidence-based framework as to the adequacy of the current standard?

The use of exposure/risk information from the previous Pb NAAQS review appears appropriate given the absence of significant new information that could fundamentally change the interpretation of the exposure/risk information. This interpretation is reasonable given that information supporting the current standard is largely unchanged since the current standard was issued.

The CASAC agrees that the adverse impact of low doses of Pb on neurocognitive function and development in children remains the most sensitive health endpoint, and that a primary Pb NAAQS designed to protect against that effect will offer satisfactory protection against the many other health impacts associated with Pb exposure.

The CASAC concurs with the draft PA that the scientific findings pertaining to air-to-blood Pb ratios and the C-R relationships between blood Pb and childhood IQ decrements that formed the basis of the current Pb NAAQS remain valid and are consistent with current data.

In reaching preliminary staff conclusions, staff notes that, like any NAAQS review, this Pb NAAQS review requires public health policy judgments. The public health policy judgments for this review include the public health significance of a given magnitude of IQ loss in a small subset of highly exposed children (i.e., those likely to experience air-related Pb exposures at the level of the standard), as well as how to consider the nature and magnitude of the array of uncertainties that are inherent in the evidence and in the application of this specific framework.

What are the Panel's views on public health policy judgments that inform staff's preliminary conclusions with regard to the adequacy of current standard and a lack of support for consideration of potential alternative standards?

The PA states repeatedly that no threshold for Pb effects on IQ can be identified. In some respects, the ability to define a threshold may already be a moot issue. Reductions in IQ in children are being reported at blood Pb values as low as 2 µg/dL. In essence, these effects are being reported at the lowest levels of Pb in blood that can be reliably measured by most laboratories doing such analyses.
Child IQ is the Pb-sensitive health endpoint on which this PA (and the previous one) is based. Thus, the discussion of health policy judgment needs to be carefully considered in light of the far-reaching public health value of childhood cognitive and neurobehavioral health. For example, the 2012 Centers for Disease Control and Prevention (CDC) update of recommendations regarding childhood Pb poisoning acknowledges that there is no blood Pb level in childhood that is safe from potential neurocognitive toxicity. In this context, defining the threshold for "unacceptable risks to public health" or "sufficient

public health protection" is difficult. Indeed, such language - with its implicit use of a threshold approach to a process that presumably has no threshold - may no longer be appropriate.

Although the Clean Air Act regulation does not require that zero risk be achieved, neither does it prevent it. Given the above statement, and the fact that the supra-linear C-R curve has now been demonstrated in several studies, it becomes a risk management and risk communication challenge to posit a standard based on implicit acceptance of a 1-2 IQ point loss. From a biological perspective, a standard based on some degeneration of function does not seem appropriate. From a public health perspective, communicating to the public that a regulatory standard is based on exposures that provide no more than a 1-3 point IQ reduction would seem less than ideal and contradictory to their expectations. Refining the Pb NAAQS through additional research priorities as listed below may assist in this regard.

In the Panel's view, does the discussion in section 4.3 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that it is appropriate to consider retaining the current standard (including the indicator, level, averaging time, and form) without revision?

Given the evidence-based framework, the discussion in section 4.3 provides an appropriate and sufficient rationale to support retaining the current standard without revision. For example, there is discussion in the PA regarding the choice of indicator level. However, there should be more description of supporting data and rationale behind the recommendation for the averaging time and form of the current standard.

The CASAC concurs that the new science does not support lowering the Pb NAAQS from its current level (0.15 $\mu g/m^3$). Additionally, the CASAC concurs with the caveats provided about the uncertainty in the science behind the NAAQS for Pb. In particular it appreciates and affirms a key point on page 4-28, lines 2-3: "We also recognize increased uncertainty in projecting the magnitude of blood Pb response to ambient air Pb concentrations at and below the level of the current standard." Likewise, the key idea on page 4-32, lines 32-35 is important, but a clarifying revision is recommended as follows:

> Page 4-32, lines 32-35, current text: "In staff's view, based on current evidence there is appreciable uncertainty associated with drawing conclusions regarding whether there would be reductions in risk to public health from alternative lower levels as compared to the level of the current standard." This should be re-written to read "In staff's view, based on current evidence there is appreciable uncertainty associated with drawing conclusions regarding whether there would be reductions in ***blood lead levels*** from alternative lower levels as compared to the level of the current standard."

Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

As noted above, repeated statements about a threshold do not seem warranted given that IQ reductions now occur at the lowest blood Pb levels that can be reliably measured in most laboratories. It is for this

reason that the Advisory Committee for Childhood Lead Poisoning Prevention Committee recommended to CDC a complete elimination of the phrase 'level of concern' and stated that no safe level of blood Pb can be identified.

The EPA should encourage development of research programs to address those limitations and uncertainties in currently available evidence (and exposure/risk information) that are critical to the identification of "sufficiently health protective" air Pb standards in the future.

There are some areas that need revision for clarity:

- Page 4-34, line 13: The statement should be edited to: "Factors affecting relationships between Pb in ambient air and Pb in blood ***at low exposures experienced in the general population today"***
- Page 4-34, lines 19-21: This research need is profound, but as written is too vague to be appreciated by the average reader. This research need should be revised to: "Apportionment of blood Pb levels with regard to exposure pathways, with particular focus on understanding exposure pathways and sources that cause the more elevated blood Pb levels among children today."

<u>Research Needs</u>

Several areas of research that could assist in further refinement of the Pb NAAQS include:

1. For the purposes of policy and decision making, ***key*** research priorities should be studies that elucidate: (1) the air-blood Pb relationship at low levels; (2) sources (exposure pathways) contributing to current population blood Pb levels, especially in children; (3) the relationship between Pb and childhood neurocognitive function at current population exposure levels; and (4) the relationship between ambient air Pb and outdoor dust and surface soil Pb concentrations, *including the temporal dynamics of that relationship*. These research priorities are of particular interest because of the prominent contribution of past (as opposed to recent) Pb emissions to Pb in soil and dust, and the significant contribution of dust and soil matrices to the Pb exposure of children.

2. For the typical American adult not subject to current or past point sources or occupational Pb exposure, Pb in the diet is likely to constitute the largest fraction of daily Pb exposure. Therefore, another research need of considerable interest is to determine the source of contemporary dietary Pb, including the indirect contribution of historical air Pb emissions (i.e. "legacy Pb"). Further, there remains a need to determine how much of dietary Pb is from legacy and how much can be amenable to interventions.

3. The shape of the C-R curve for IQ reductions at extremely low levels requires further clarification. In addition, studies on more sensitive endpoints in the domain of emotion and

behavior regulation are warranted, given that they may yield specific and sensitive measures and thereby assist in defining appropriate intervention strategies for children.

4. There has been a long-term reliance on the Integrated Exposure Uptake Biokinetic (IEUBK) model. However, greater understanding of inter-individual variability, as quantified in the Geometric Standard Deviation (GSD) input parameter, is needed. Information about toxicokinetics during adolescence remains limited. The All Ages Lead Model could be utilized to improve this understanding. There is also the need to know more about gene-environment interactions, particularly in driving inter-individual susceptibility and vulnerability.

5. Characterization and better understanding of Pb exposure hotspots/sources will give better representation of significant exposure risks.

6. Understanding of the impacts of Pb exposures during critical developmental windows and their contribution to adverse outcomes; e.g., little is known about the specific effects of prenatal exposure.

7. The effect of contemporary Pb exposure (i.e., that resulting in blood Pb concentrations on the order of 5 µg/dL or lower) on the future risk of hypertension and cardiovascular morbidity and mortality, and on age-related neurodegeneration, as these could lead to additional information related to most sensitive health outcomes.

8. A further understanding of the role of "reverse causation" in the inverse association observed in some studies between low blood Pb concentration and renal function (e.g., glomerular filtration rate).

9. The extent to which product substitution, i.e., replacement of Pb with less hazardous alternative substances in contemporary commerce, may result in reduction of human Pb exposure. The EPA might consider supporting studies on Pb potentially undertaken by programs such as the Toxic Use Reduction Program in Massachusetts, and the Green Chemistry Initiative in California.

10. As yet, the extent to which global warming will influence exposure to Pb (e.g., through soil erosion, resuspension) has not been evaluated.

Chapter 5 – Welfare Effects and Exposure/Risk Information

This chapter discusses key policy relevant aspects of the environmental evidence and exposure/risk information.

Chapter 5 of the PA is a well-written synthesis of the findings related to ecological effects in the ISA. The ISA supports the conclusion that recent research has not changed our fundamental understanding of Pb fate, transport and toxicity in the environment.

To what extent does the information in section 5.1 (Welfare Effects Information) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?

Section 5.1 does a good job of summarizing the evidence for ecological effects from the ISA. The general conclusion is that recent research has added depth and nuance to the understanding of the fate and transport of Pb in ecological systems, and to the understanding of effects on organisms in terrestrial and aquatic ecosystems, but has not changed the understanding in a way that merits reconsideration of the relationships used to assess risk.

A persistent theme in the ecological effects sections of the ISA and this PA document is that it is difficult to isolate the effects of air Pb on ecosystems from other Pb sources, including "legacy" Pb accumulated in soils and sediments. The threat of release of legacy Pb in soils and sediments, whatever the original source, may necessitate a lower secondary air quality standard than would be warranted in the absence of the legacy Pb. Similarly, Pb in ammunition is known to have adversely affected bird populations, which may justify a lower air Pb standard.

With regard to the exposure and risk information in section 5.2 (Exposure and Risk Information), to what extent is the information drawn from the screening-level risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the current standard?

The results of the 2006 REA are summarized in section 5.2. The summary is concise and clear, both in the explanation of the model employed and in the descriptions of the case studies used in the assessment.

The interpretation of the results from the 2006 REA is appropriate insofar as it re-states the conclusions from that document, and there have been no fundamental changes to our understanding of key thresholds or ecological receptors in the intervening years. Of four terrestrial case studies employed, the results from two (the primary and secondary smelter cases) are judged to be "not informative." The relevance of a third case study (non-urban near-roadway conditions) is deemed "highly uncertain" due to the presence of legacy Pb in roadside soils. The only terrestrial case study that is deemed relevant is the Hubbard Brook case, where ambient Pb concentrations are far below the current (and proposed) standard. Results from analysis of surface water and sediment data are judged to be inconclusive because of possible non-air sources to waters and legacy Pb in sediments. Therefore, overall, four of the five major efforts in the 2006 REA are judged to be of limited or no value for the purposes of this PA. Given that there is little field research underway on Pb in U.S. ecosystems that are not impacted by point sources, it would appear to be unlikely that data for new REA case studies is forthcoming. A robust critical loads approach, which is a research priority to support a future review, is needed to fill this gap.

Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?

The discussion of limitations and uncertainties is generally good. Issues such as legacy Pb, multi-stressor effects, and lab-to-field applicability create considerable uncertainty. The use of conservative screening levels in the calculation of hazard quotients is particularly useful because the calculated risks are overstated.

Chapter 6 – Review of the Secondary Standard for Lead

This chapter describes the basis for the current secondary standard and consideration of the current evidence and exposure/risk-based information with regard to reaching preliminary staff conclusions about the adequacy of the current standard.

Does the Panel agree with preliminary staff conclusions about the evidence and previous risk assessment in light of current standards as presented in section 6.2 (Adequacy of the Current Standard)?

The preliminary staff conclusions provide a good assessment of the available evidence and the previous risk assessment in light of the current secondary standard. The CASAC notes, however, the concerns raised in the response to the chapter 5 charge questions regarding the previous risk assessment.

In the Panel's view, does the discussion in this chapter provide an appropriate and sufficient rationale to support preliminary staff conclusions that it is appropriate to consider retaining the current standard (including the indicator, level, averaging time, and form) without revision?

The discussion provides appropriate and sufficient rationale to support retaining the current secondary standard without revision. A general lack of new data that would indicate the appropriate level of Pb in environmental media that may be associated with adverse effects suggests that the secondary standard should be retained. Questions remain regarding the relevance of the indicator, level, averaging time and form to the secondary standard (ecological context). A multi-media approach may be necessary to account for legacy Pb and contributions from different sources for a secondary standard.

Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

The CASAC does not have any recommendations regarding additional interpretations and conclusions beyond what is contained in the chapter. Developing a critical loads approach for U.S. conditions would be an important area for additional research. The discussion of uncertainties at the end of the chapter is excellent. It should include mention of the use and/or relevance of toxicity data that are generated in test systems that deploy exposures to media other than soil or water for appropriate organisms (e.g., plants in hydroponic systems, soil nematodes in agar or culture medium).

Research Needs

Application of a critical loads approach with sensitivity analysis will help to determine which processes are most important in determining Pb exposure to ecological receptors. This would be an integrated, holistic, multi-media approach that could be used to examine the contributions of current aerial Pb deposition to historical aerial deposition as well as Pb from other sources. Current critical loads models are largely qualitative and empirical. Mechanistic sub-models need to be incorporated into the critical loads model to provide an adequate means to predict Pb bioavailability, exposure, and toxicity. This critical loads approach could be integrated to include other aerial pollutants such as oxides of nitrogen and oxides of sulfur.

Appendix A

Compendium of Individual Comments by CASAC Lead Review Panel Members on EPA's Policy Assessment for the Review of the Lead National Ambient Air Quality Standards (External Review Draft – January 2013)

Mr. George A. Allen

Comments on Chapter 2

Response to specific Charge Questions:

1. To what extent does the Panel agree that the most relevant information on emissions (section 2.1), air quality (section 2.2.2), and Pb concentrations in other media (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

Overall, Chapter 2 provides a concise and well-organized summary of the relevant material from the ISA. Minor note: the boxplots in section 2.2.2 need to have the whisker defined - is it 95th percentile?

2. With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

2.2.1.3.1, pg 2-20, lines 4-9: this paragraph is a well written description of the process being taken towards a better FRM sampler. It states that known limitations in wind-tunnel aerosol generation and particle sampling of ultra-coarse particles will limit the upper range of any new FRM to 18-20 microns. I would suggest that EPA consider the practical aspects of sampler design and testing, and (at least initially) constrain the project goals to an upper limit of 15 microns, a size noted in the ISA as being appropriate (sufficiently large enough) for exposure assessment in a NAAQS context.

2.2.1.3.3, Pg. 2-22, lines 17-18: The Pb NAAQS form is "never to be exceeded" – a unique form. How is the Pb design value calculated - is it the highest 3-month running average over the 3-year period?

Dr. Herbert Allen

Comments on Chapter 5

Generally this Chapter is well-written and follows the important information in the ISA. There are several places that need attention.

Page 5-5 lines 27-30. This sentence references section 7.4.24 of the ISA. However, the ISA does not contain a section 7.4.24. The statement that "dissolved organic carbon and DOM [i.e., dissolved organic matter] do not have the same effect on free lead ions" is very misleading. Dissolved organic carbon is not a substance. It is means of expressing the concentration of the carbon contained dissolved organic matter and is typically used to express the results of instrumental carbon analysis.

Page 5-6 line 35 – page 5.7 line 2. The lead concentration of 2.5 µM is not a concentration in soil, but the concentration in a solution to which the nematodes were exposed.

Page 5-19 line 15. Rather than "from 5 ppb to about 5 ppt" it would be more appropriate to write "from 5 µg/L to 5 ng/L".

Comments on Chapter 6

I believe this Chapter is acceptable as written. The conclusions are clearly stated and justified.

Dr. Richard Canfield

Comments on Chapter 3: Health Effects and Exposure/Risk Information

1. *To what extent does the information in sections 3.1 (Internal Disposition and Biomarkers of Exposure and Dose), 3.2 (Nature of Effects) and 3.3 (Public Health Implications and At-Risk Populations) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?*
    a. This draft PA generally captures the key aspects of the evidence presented in the ISA and so any concerns about content are related to the content of the ISA and not its condensation in the PA.
    b. Recognizing the degree of condensation needed to summarize the ISA in only a few pages, this format presents a great writing challenge, and the clarity of writing in this chapter betrays its status as a "draft." During revision it will be important to reduce wordiness in order to convey the meaning more directly and efficiently. For example, sentences such as the following could be shortened and recast in a more active voice: "The results from the various case studies assessed, with consideration of the context in which they were derived (e.g., the extent to which the range of air-related pathways were simulated, and limitations associated with those simulations), and the multiple sources of uncertainty (see section 3.4.7 below) are also informative to our understanding of air-to-blood ratios." I will note in my specific comments below the sentences I found most in need of streamlining and clarification.
    c. In addition, there are a few places where legacy text from the previous PA remains and so extraneous words need to be deleted and tenses updated. What needs the most attention is the length and complexity of some sentences

2. *To what extent is the newly available evidence on air-to-blood ratios appropriately characterized and considered in light of information previously available in past reviews?*
    a. The new information on air-to-blood ratios is presented in context of previous information and it is evident why no change in the estimate is justified at this time.
    b. When revising this section (3.1) it would be helpful to first read the last (summary paragraph) on page 3-14. Those conclusions should be included in the first paragraph of the section and then restated at the end of the section when the reader will be in a position to understand the context.

3. *To what extent is the newly available evidence on concentration-response functions for IQ decrements in young children appropriately characterized and considered in light of information previously available in past reviews?*
    a. The newly-available evidence is appropriately characterized. Parametric information could be extracted from these data to produce quantitative results for blood Pb subgroups, but I do not believe the quality of the data would provide a useful basis for altering the conclusions reached from the data available prior to 2008.
    b. EPA has correctly identified the lack of information about effects of Pb at levels in the 0-5 ug/dL range. Such a study should be done.

4. *With regard to the exposure and risk information, to what extent is the information drawn from the human exposure and health risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the now current standard?*
    a. Information from the last review is well-characterized and appropriately interpreted. Clarity of communication can be improved.
    b. Putting the conclusion in the first paragraph of the section was very helpful. I concur that a new REA is not warranted at this time.

5. *Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?*
    a. Limitations and uncertainties are well characterized.
        i. Epidemiological data are inherently limited; *viz.*, there is a lack of data on the effects of Pb exposure at the levels that are common today and thus C-R estimates require excessive extrapolation.
        ii. Parameter choices for biokinetic models typically require restrictive assumption.
        iii. No single air quality scenario is adequate.

<u>Other comments:</u>

3-19 lines 23-24: It might be clearer to use the phrase “qualitatively change” rather than “appreciably change” to allow for appreciable strengthening of the previous conclusion but no change of consequence.

3-21 Table 3-2 and elsewhere: I suggest reconsidering whether 24-month Bayley data are sufficiently strong to mention in this high-level review. [note that the table includes lots of measures besides IQ

3-22 lines 17-23: This is a nice discussion of the problem with unknown earlier exposures in adults and older children. It comes up multiple times throughout this document and becomes redundant. Maybe this should be covered fully (including this as a general critique of cross-sectional studies), early in the chapter and then simply referred back to when the context warrants.

Dr. Deborah Cory-Slechta

Comments on Chapter 4 – Primary Standard for Lead

To what extent does the Panel agree with the application of the evidence-based framework from the last review, particularly with regard to consideration of the currently available information, and related limitations with uncertainties, for air-to-blood ratios and C-R functions for IQ decrements in young children?

The application of the evidence-based framework from the last review seems appropriate, particularly given that new literature since the prior 2006 review provides further support for the health effect conclusions presented in the prior review. Additionally, new studies do not fundamentally alter the uncertainties for air-to-blood ratios or C-R functions for IQ decrements in young children.

What are the Panel's views on staff's interpretation of the exposure/risk information, and on staff's conclusions that the information is generally supportive of conclusions drawn from the evidence-based framework as to the adequacy of the current standard?

The use of exposure-risk information from the prior review appears appropriate given the absence of significant new information that could fundamentally change the interpretation.

What are the Panel's views on public health policy judgments that inform staffs' preliminary conclusions with regard to the adequacy of the current standard and a lack of support for consideration of potential alternative standards?

The document states repeatedly that no threshold for lead effects on IQ can be identified. In some respects, the ability to define a threshold may already be a moot issue. Reductions in IQ in children are being reported at blood lead values as low as 2 ug/dl. In essence, these effects are being reported at the lowest levels of lead in blood that can be reliably measured by most laboratories doing such analyses.

While the regulations do not require that zero risk be achieved, neither does it prevent it. Given the above statement, and the fact that the supra-linear C-R curve has now been demonstrated in several studies, it becomes increasingly difficult to support a standard based on 1-2 IQ point loss. From a biological perspective, a standard based on some degeneration of function does not seem appropriate. From a public health perspective, communicating to the public that a regulatory standard is based on exposures that provide no more than a 1-3 point IQ reduction would seem less than ideal and contradictory to their expectations.

In the Panel's view, does the discussion in section 4.3 provide an appropriate and sufficient rationale to support staff's preliminary conclusion that it is appropriate to consider retaining the current standard (including the indicator, level, averaging time, and form) without revision?

Yes, given the evidence-based framework. However, given that we are now down to the lowest blood lead levels that can be reliably measured, it is not clear that all of these arguments are in fact requisite.

Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?

As noted above, statements about the threshold do not seem warranted given that IQ reductions now occur at the lowest blood lead levels that can be reliably measured in most laboratories. It was for this reason that the ACCLPP committee recommended to CDC a complete elimination of the phrase 'level of concern' and stated that no safe level of blood lead can be identified.

Dr. Cliff Davidson

Comments on Chapter 1

Chapter 1 of the PA is generally well written and easy to follow. It is a reasonable introduction to the rest of the PA document.

Page 1-2, lines 21-24 state that a new Risk and Exposure Assessment was found to be unnecessary at this time, and hence the health and welfare REAs developed for the 2006 review are adequate for use with current environmental concentration and exposure data. This is clearly presented and is justified based on our prior committee reviews.

Section 1.3.2 discusses considerations related to the history of Pb emissions during the days of leaded gasoline and high stationary source emissions. The section correctly points out that the current task is to assess the adequacy of the current airborne Pb standard, while recognizing that there is a history of high Pb emissions. But what is missing from this section is an appreciation for the magnitude of the past Pb emissions.

A simple calculation illustrates the point. Figure 3-1 in the ISA (page 3-3) which is repeated as Figure 2-1 in the PA (page 2-3) shows that total Pb emissions in the year 1970 were over 200,000 tons of Pb. The PA should put this value into perspective. If we conservatively pick 10 years of emissions at this level, we obtain about 2 million tons of Pb emitted. Clearly, the total Pb emissions are more than this value. But some of this Pb was carried out of the U.S., where it eventually deposited in the oceans or elsewhere. It is not unreasonable to assume that about 2 million tons of Pb deposited within the boundaries of the U.S. as a very rough value. If this Pb deposited uniformly over the entire land area of continental U.S., around 25 micrograms of Pb would have deposited per cm^2 of surface. This is roughly equal to the natural amount of Pb in the top 1 cm of soil (12.5 ppm = 12.5 micrograms of Pb per gram of soil, or about 25 micrograms per cm^3 assuming a soil density of 2 grams per cm^3). We have thus approximately doubled the amount of Pb in the top cm of soil throughout the continental U.S. It is apparent that soil in some areas, especially urban areas, will contain much more than this, while larger remote areas will contain less.

The point of this calculation is that we do not know the ultimate fate of roughly 2 million tons of Pb deposited during the days of leaded gasoline, a value that dwarfs current emissions. We suspect that most of this huge amount of Pb is now stored in the environment, with significant amounts in U.S. urban areas where population densities are greatest. The fact that we cannot account for this lead constitutes a major uncertainty in our understanding, and it merits a discussion to that effect in the PA.

There is one sentence in need of revision for accuracy, namely on page 1-13 line 35:

"And we recognize that past lead emissions in many situations were well in excess of the current Pb standard." One cannot compare emissions to an airborne standard. One way to fix this sentence is to

write: "And we recognize that past lead emissions in many situations caused airborne lead concentrations far in excess of the current Pb standard."

Dr. Sean Hays

General Comments on Chapter 4

- I agree with the caveats provided about the uncertainty in the science behind the NAAQS for lead. In particular I agree with, and appreciate EPA adding, the following statements.
    - Page 4-28, line 2-3: "We also recognize increased uncertainty in projecting the magnitude of blood Pb response to ambient air Pb concentrations at and below the level of the current standard"
    - Page 4-32, lines 33-35: "In staff's view, based on current evidence there is appreciable uncertainty associated with drawing conclusions regarding whether there would be reductions in risk to public health from alternative lower levels as compared to the level of the current standard". This should perhaps be re-written to read "In staff's view, based on current evidence there is appreciable uncertainty associated with drawing conclusions regarding whether there would be reductions in blood lead levels from alternative lower levels as compared to the level of the current standard
- I agree that the new science does not support lowering the NAAQS any lower than its current level (0.15 ug/m^3).

Specific comments on Chapter 4

- Page 4-34, line 13: The following statement should be edited to; "Factors affecting relationships between Pb in ambient air and Pb in blood at low exposures experienced in the general population today"
- Page 4-34, lines 19-21: This statement is profound, but as written is too vague to be appreciated by the average reader. I would recommend editing to be something along the lines of; "Apportionment of blood Pb levels with regard to exposure pathways, with particular focus on understanding exposure pathways and sources that cause the more elevated blood lead levels among children today. "

Dr. Philip Hopke

I would like to start with a broad comment. I would hope we could see the United States moving to eliminate a NAAQS for airborne lead. Now is not yet the time, but this should be part of the discussion in the next round of review. If we eliminate lead in aviation gas and in wheel weights, we will have removed the remaining major dispersed sources of lead other than resuspended soil. All of the remaining point sources whether lead or other metal processing could be handled under HAPs rules. We will need to eliminate these final sources (aviation gasoline in particular), but then it is time for a serious discussion of the further need for a lead NAAQS or whether the resources that currently go into this process would be better used to address other widely dispersed pollutants from multiple sources such as benzene or mercury.

Comments on Chapter 2

1. To what extent does the Panel agree that the most relevant information on emissions (section 2.1), air quality (section 2.2.2), and Pb concentrations in other media (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

Staff has done a good job of summarizing the information from the ISA. The chapter provides a good background to the discussions in the following chapters.

2. With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

The statistical justification for a never to be exceeded standard has never been presented. It is a hangover from prior standards that does not seem to have been adequately considered and reviewed. Given the natural variability of the environment, this form of the standard represents a poor coupling of science to reality and it would be much better if the form of the standard better reflected that control should be based on the distribution of lead concentrations. Other forms of the standard can be set to be highly restrictive on the range of concentrations so as to provide the requisite protection of public health while still recognizing the variable nature of the system. It would be useful to see an adequate statistical discussion of the standard form and a justification that this form is appropriate to provide the protection required.

Dr. Chris E. Johnson

Comments on Chapter 5: Welfare Effects and Exposure/Risk Information

To what extent does the information in section 5.1 (Welfare Effects Information) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?

Section 5.1 does a good job of summarizing the evidence for ecological effects from the Third Draft ISA. Each sub-section includes a brief description of our understanding in the 2006 Air Quality Control Document, and commentary on how research undertaken since then has (or has not) changed our understanding. The general conclusion is that recent research has added depth and nuance to our understanding of the fate and transport of Pb in ecological systems, and to our understanding of effects on organisms in terrestrial and aquatic ecosystems, but has not changed our understanding in a way that merits reconsideration of relationships used to assess risk.

Two persistent themes in the ecological effects sections of the ISA and this PA document are: (1) it is difficult to isolate the effects of air Pb on ecosystems from other sources, including "legacy" Pb accumulated in soils and sediments; and (2) it is difficult to isolate the effects of Pb from other metals and stressors. It is distressing to see the degree to which these explanations are used to justify no-action conclusions. The threat of release of legacy Pb in soils and sediments, for example, whatever the source (atmospheric or geologic), may necessitate a lower secondary air quality standard than would be warranted in the absence of the legacy Pb.

The overall impression left in reading section 5.1 is that the authors are working very hard to justify a no-action conclusion, even if that means forcing some round pegs into square holes.

With regard to the exposure and risk information in section 5.2 (Exposure and Risk Information), to what extent is the information drawn from the screening-level risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the current standard?

The results of the 2006 risk and exposure assessment (REA) are summarized in section 5.2. The summary is concise and clear, both in the explanation of the model employed and in the case studies used in the assessment.

The interpretation of the results from the 2006 REA is appropriate insofar as it re-states the conclusions from that document, and there have been no fundamental changes to our understanding of key thresholds or ecological receptors in the intervening years. However, after reading section 5.2 of the draft PA, one is left with serious doubts about the value of the original work for the purpose of establishing a secondary standard. Of four case studies employed, the results from two (the primary and secondary smelter cases) are judged to me "not informative." The relevance of a third case study (non-urban near-

roadway conditions) is deemed "highly uncertain" due to the presence of legacy Pb in roadside soils. The only case study that is deemed relevant is the Hubbard Brook case, where ambient Pb concentrations are far below the current (and proposed) standard. Results from analysis of surface water and sediment data are judged to be inconclusive because of possible non-air sources to waters and legacy Pb in sediments.

Overall, four of the five major efforts in the 2006 REA are judged to be of limited or no value for the purposes of this policy assessment. Yet the Agency considers another REA unnecessary. Perhaps new information since the 2006 REA does not warrant a new REA, but the apparent inadequacy of the 2006 REA would certainly seem to warrant another try.

Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?

As discussed above in my comments to the other charge questions, I believe that the limitations and uncertainties presented in chapter 5 of the Draft PA are somewhat overstated. Issues such as legacy Pb, multi-stressor effects, and lab-to-field applicability do create uncertainty, but do not make data uninformative.

Dr. Susan Korrick

Comments on Chapter 4

General Comment:

This Draft Policy Assessment (PA) is constrained by the absence of appreciable new observational and experimental data that addresses, at least in part, limitations and uncertainties in the evidence that were present at the time of the last update of the NAAQS for Pb. Assuming the approach used in the previous PA was appropriate at the time, by default, it is reasonable to extend it now. However, this circumstance underscores a fundamental dilemma. That is, until evidence is available to assess Pb exposure and health risks related to air Pb levels reflecting the current standard, a substantive refinement and update of the PA will not be possible. The obvious and most fundamental uncertainty underlying evaluation of this PA is whether lowering the standard would (or would not) impact exposure risk. If lowering the standard would be beneficial to BPb levels, then there would be potential for additional public health benefit from a lower standard. However, such information is currently unknown.

1. *"To what extent does the Panel agree with application of the evidence-based framework from the last review, particularly with regard to consideration of the currently available information, and related limitations and uncertainties, for air-to-blood ratios and C-R functions for IQ decrements in young children?"*

Application of the evidence-based framework from the last review is reasonable given that there is no new information available since the last review that would improve our understanding of air-to-blood ratios or C-R functions for IQ at low-level exposures nor that would address previously identified limitations and uncertainties in the available evidence. (See my general comment above).

Uncertainties in evidence-based information (and exposure/risk estimates) are emphasized and enumerated repeatedly throughout this Chapter. However, there are information sources that could be used to address, at least qualitatively, some of these uncertainties. For example, elevated air lead levels in the workplace result in relatively rapid increases in blood Pb levels. (Admittedly, extrapolation of the occupational setting to low level exposures in pregnant women and children is uncertain and the timing of achieving steady state Pb levels may be uncertain). Still, human epidemiologic data, in turn, support Pb exposure over a trimester of pregnancy as being a potentially important determinant of subsequent neurocognitive development. With such information, one could estimate that exposures occurring over a period of months, if not an even shorter period, are likely relevant for certain critical windows of child development.

2. *"What are the Panel's views on staff's interpretation of the exposure/risk information, and on staff's conclusions that the information is generally supportive of conclusions drawn from the evidence-based framework as to the adequacy of the current standard?" (no new REA, use REA from last review)*

This interpretation is reasonable given that information supporting the current standard is largely unchanged since the current standard was issued. (See my general comment above).

3. *"What are the Panel's views on public health policy judgements that inform staff's preliminary conclusions with regard to the adequacy of current standard and a lack of support for consideration of potential alternative standards?"*

Child IQ is the Pb-sensitive health endpoint on which this PA (and the previous one) is based. Thus, the discussion of health policy judgements needs to be carefully considered in light of the fundamental and far reaching public health value of childhood cognitive and neurobehavioral health. For example, the 2012 CDC update of recommendations regarding childhood lead poisoning includes acknowledgement that there is no blood Pb level in childhood that is safe from potential neurocognitive toxicity. In this context, defining the threshold for "unacceptable risks to public health" or "sufficient public health protection" is difficult. Indeed, such language with its implicit use of a threshold approach to a process that presumably has no threshold may no longer be appropriate.

4. *"In the Panel's view, does the discussion in section **4.3** provide an appropriate and sufficient rationale to support staff's preliminary conclusion that it is appropriate to consider retaining the current standard (including the indicator level, averaging time, and form) without revision?"*

The short answer is "yes". However, it would be helpful if there was more description in the PA of the data and rationale behind the averaging time and form of the current standard. In contrast, there is some discussion in the PA regarding the choice of indicator level. (Also, see my general comment above).

5. *"Does the Panel have any recommendations regarding additional interpretations and conclusions based on the available information that would be appropriate for consideration beyond those discussed in this chapter?"*

I have no recommendations except to encourage development of research programs to address those limitations and uncertainties in currently available evidence (and exposure/risk information) that are critical to the identification of "sufficiently health protective" air Pb standards in the future.

For the purposes of policy and decision making, I recommend that key research priorities include studies to elucidate: (1) the air-blood Pb relationship at low levels, (2) sources (exposure pathways) contributing to current population blood Pb levels, especially in children, and (3) the relationship of Pb with childhood neurocognitive function at current population exposure levels.

Dr. Michael Kosnett

1. I concur with the key finding of draft Policy Assessment (PA) that the currently available information supports a primary standard as protective as the current standard, and that it is appropriate to retain the current standard without revision at this time.

2. I agree that the adverse impact of low doses of lead on neurocognitive function and development in children remains the most sensitive health endpoint, and that a NAAQS designed to protect against that effect will offer satisfactory protection against the many other health impacts associated with lead exposure. I agree with the findings in the draft PA that the scientific findings pertaining to air-to-blood lead ratios and the concentration-response relationships between blood lead and childhood IQ that formed the basis of the current NAAQS remain valid and are consistent with current data. I further agree with EPA's prior assessment that from a public health standpoint, "an IQ loss on the order of one to two IQ points [should] be prevented in all but a small percentile of the population."

3. I concur with the recommendations suggested in Section 4.4 "Key Uncertainties and Areas for Future Research and Data Collection." I particularly agree with the recommendation in the last bulleted section on page 4-35 that reads:

> An important aspect to this review is the relationship between ambient air Pb and outdoor dust and surface soil Pb concentrations, *including the temporal dynamics of that relationship* …. [emphasis added].

This research point is of particular interest because of the prominent contribution of past (as opposed to recent) lead emissions to lead in soil and dust, and the significant contribution of dust and soil matrices to the lead exposure of children.

For the typical American adult not subject to current or past point sources or to occupational lead exposure, lead in the diet constitutes the largest fraction of daily lead exposure. Therefore, another research question of considerable interest would investigate the source of contemporary dietary lead, including the indirect contribution of historical air lead emissions (i.e. "legacy lead").

Additional research questions of considerable importance include the following:

• The effect of contemporary lead exposure (i.e. that resulting in blood lead concentrations on the order of 5 ug/dL or lower) on the future risk of hypertension and cardiovascular morbidity and mortality, and on age-related neurodegeneration.

• The role of "reverse causation" in the inverse association observed in some studies between low blood lead concentration and renal function (glomerular filtration rate).

• The extent to which product substitution, i.e. replacement of lead with less hazardous alternative substances in contemporary commerce, may result in reduction of human lead exposure. EPA might consider supporting studies on lead potentially undertaken by programs such as the Toxic Use Reduction Program in Massachusetts, and the Green Chemistry Initiative in California.

4. The PA, particularly in Chapter 5, should acknowledge the contribution of lead in spent ammunition to the critical load of lead in certain ecosystems, and the important contribution that this source has on certain ecological receptors such as raptors and other large birds. Recent evidence confirms that these species are among the most heavily lead poisoned, sometimes to the point of death (Watson RT, Fuller M, Pokras M et al [eds] Ingestion of Lead from Spent Ammunition: Implications for Wildlife and Humans. Peregrine Fund: Boise, ID, 2009). The incremental contribution of air Pb to the food chain and ecosystem of fauna impacted by spent Pb ammunition therefore takes on considerable importance.

5. The following statements in the draft PA should be subject to revision:

Page 3-2, Line 15 referring to distribution of lead from bone to blood, includes the sentence: "Changes in Pb exposure circumstances can also influence these exchanges, e.g., substantial reductions in exposure levels contribute to increased release of Pb from the bone into the blood (ISA, section 4.3.5)." This sentence should be revised, as it appears to incorrectly characterize the information in section 4.3.5 of the ISA. A reduction in external lead exposure does not, from a pharmacodynamic standpoint, induce an increase in the release of lead from bone. In the context of the paragraph, the intended point could be expressed as follows: "When there are substantial reductions in external Pb exposure, the relative contribution of Pb from bone to the concentration of Pb in blood increases."

Page 3-5, line 29 to Page 3-6, line 9: The italicized sentence in this paragraph, reproduced below, should be revised to improve clarity:

> The response of adult blood Pb levels to appreciable changes in exposure circumstances is generally slower than that of blood Pb levels in young children. For example, simulations using biokinetic models indicate that blood Pb levels in adults achieve a new quasi-steady state within 75-100 days (approximately 3-4 times the blood elimination half-life) subsequent to abrupt increases in Pb intake (ISA, section 4.3.5.2); similar models indicate a much quicker response of blood Pb levels in children both with regard to abrupt increases and reductions in Pb exposure (ISA, section 4.3.5.1). *The response in young children may reflect their much more labile bone pool associated with the rapid turnover of bone mineral in response to their rapid growth rates (ISA, section 4.3.5*). As a result of these physiological processes in young children, their blood Pb levels tend to more quickly reflect changes in their total body burden (associated with their shorter exposure history), and can also reflect changes in recent exposures (ISA, section 4.3.5).

Instead of the italicized sentence above, substitution of a sentence such as the following might enhance clarity: "Because the skeletal compartment of Pb is relatively smaller and subject to more rapid turnover in children compared to adults, the blood Pb concentration of children is more reflective of their recent external exposure."

Page 3-24, footnote 22. The units for blood lead cited here should be "µg/dL", not "µg/m3".

Page 4-24, footnote 9. This footnote, reproduced below in its current form, could be editorially revised to improve clarity. This might be accomplished by rewriting it as two shorter sentences, instead of the current long sentence:

> "We note that the value of the upper bound is influenced by risk associated with exposure pathways that were not varied with alternative standard levels, a modeling limitation with the potential to contribute to overestimation of the upper bound with air quality scenarios involving air Pb levels below current conditions for the study area (see sections 3.4.4 and 3.4.7 above)."

Dr. Roman Lanno

The Policy Assessment document (did not read chapters 3 and 4) is well written and summarizes evidence justifying retaining the current secondary standard without revision. Retaining the current standard is warranted given the lack of significant additional data that has become available since the last AQCD. The US EPA nicely describes that the new data adds to an existing database, refines some key concepts (e.g., bioavailability, critical loads), but is not yet ready for application in the development and revision of a new secondary standard. Additionally, uncertainties in Pb exposure/risk are addressed. The magnitude of the contribution of Pb from air to the total environmental Pb load and the fate and distribution of airborne Pb to other environmental media is discussed. Figure 1-1 provides a nice backdrop for discussing these issues. The confounding effects of other sources of Pb (e.g., surface runoff to waters near industries) and the "challenge of disentangling of atmospheric deposition contributions from those associated with surface runoff" are discussed. Uncertainties related to screening values used in the risk assessment are also discussed.

Page 2-1, line 11 – change "depending on their size" to "depending on particle size"
Page 2-20, lines 26 and 27 – change "adsorption" to "absorption"
Page 2-38, line 5 – What is meant by "substantially"? Is this a statistically significant decrease and if so, by how much? Half, ten-fold? Specifics would help here.
Page 2-40, line 7 – remove underscore in 20 ug/kg
Page 2-40, line 12 – Should this be Figure 2-14, not 2-16?
Page 2-41 – Figure 2-14 shows very nicely the drop in environmental Pb due to the phasing out of leaded gasoline

Chapter 2 provides an excellent summary of temporal trends in Pb exposure, especially the influence of removing Pb from automotive gasoline.

Comments on Chapter 5 - Welfare Effects and Exposure/Risk Information

To what extent does the information in section 5.1 (Welfare Effects Information) capture and appropriately characterize the key aspects of the evidence assessed and integrated in the ISA?

Section 5.1 adequately summarizes the key aspects of evidence assessed and integrated in the ISA.

With regard to the exposure and risk information in section 5.2 (Exposure and Risk Information), to what extent is the information drawn from the screening-level risk assessment in the last review sufficiently characterized and clearly communicated? To what extent is the information appropriately interpreted in light of the currently available information and for the purpose of assessing the adequacy of the current standard?

The information in section 5.2 adequately integrates and communicates the information from the screening-level risk assessment and provides an appropriate interpretation and decision on the adequacy of the current secondary standard.

Are the limitations and uncertainties in the exposure/risk information appropriately characterized and considered in our interpretation of the information in the context of this current review?

The limitations and uncertainties of both the data and the screening levels used in risk assessment of case studies are adequately discussed.

Page 5-2, lines 28-31 – another major issue is that Pb rarely occurs alone but in mixtures with other metals
Pages 5-8 and 5-9, lines 35 and 1 – in addition to the issue of single species toxicity tests not capturing the complexity of bioavailability in natural systems, there is a lack to models that integrate bioavailability information that would allow prediction of toxicity among soils varying in physical and chemical characteristics
Page 5-10, line 7 – If this data is based only upon nominal concentrations, then it should only be considered as secondary data and should be used very cautiously in a PA document. I would suggest omitting it, unless there are actual measurements of Pb in the test medium.
Page 5-15, line 5, end of line – change “summarizes” to “summarizing”

Mr. Richard L. Poirot

Comments on Chapter 2

To what extent does the Panel agree that the most relevant information on emissions (section 2.1), air quality (section 2.2.2), and Pb concentrations in other media (section 2.3) is presented, and to what extent is the information presented appropriately characterized and clearly communicated?

With a few minor exceptions (see specific comments) the information on Pb emissions, air quality and concentrations in other media is appropriately characterized and clearly presented. Historical and recent (2008) emissions data are summarized quantitatively in clear charts and tables, with additional detail on the 2008 NEI inventory data sources and limitations provided in Appendix 2A. There are also some (qualitative) discussions and an informative Appendix (2B) on recent regulatory actions, indicating that current emissions have declined since 2008, with additional reductions pending. In a future PAD, it would be useful if quantitative estimates of some of these emissions reductions could be presented.

The Information on ambient air concentrations (through 2011) is also clearly presented in maps, charts and in a detailed appendix (2D). There are more recent data (including near airports) that were initiated following the previous Pb NAAQS review, and which would be informative for the current Pb NAAQS review, as well as for the separate Section 231 avgas review. It would be useful if some of these more recent data can be presented in (or as a supplement to) the next Pb PAD. While it may take 3-years of data to calculate an official design value, an exceedance of the Pb NAAQS and other potentially useful information can be provided by as few as 3 months of new data.

The Information on Pb concentrations in other media is clearly presented. The sections (2.3.2.1 and 2.3.2.2) on indoor and outdoor dust (and air contributions to) are highly relevant to exposure assessments and would benefit from some added discussion (also missing in the ISA) of how dust Pb concentration, loading, and loading rates are measured. In particular, information relating to the differences in particle sizes in dust samples and ambient air samples would be helpful. Information on spatial gradients of Pb concentrations in soil, sediments or biota in the vicinity of large (current or former) sources could also be informative for conducting exposure assessments or for siting monitors.

With regard to information on ambient Pb monitoring (section 2.2.1), to what extent is this information appropriately characterized and clearly communicated?

The information on ambient Pb monitoring is appropriately characterized and clearly communicated. It is understood that we are "stuck" with the Hi-Vol TSP sampler as an imperfect historical artifact, and that there is not time to develop and fully test alternative samplers that would consistently capture particles greater than 10 microns with appropriate collection efficiencies and size ranges under varying wind speeds and directions. The draft PAD notes that the Agency expects a new, improved sampler to be "available for consideration in a future review". Given that the Agency had also expressed an interest in developing an alternative "TSP" sampler (low-volume TSP FRM) in the previous 2008 NAAQS

revision, it would be desirable at some point to see a commitment to expend the resources needed to have an alternative sampler "available for consideration in the next Pb NAAQS review".

Toward this goal, it would also be useful to see some discussion indicating what the desirable cut size characteristics of an alternative sampler might be. Information provided in the 3rd draft ISA could be cited here, for example (page 3-67) of the ISA: "The relevant particle size distribution for ambient sampling is smaller than the size distribution of the settled dust. Particles larger than about 20 μm are generally considered too large to be transported for more than a few seconds under typical conditions… It follows that 15 to 20 μm may be a practical limit for both good sampling data quality and representative sampling in a limited area."

Along similar lines, the term TSP is used broadly and imprecisely to mean several different things – including what the Hi-Vol collects, what other currently available so-called TSP samplers collect, and what a future alternative TSP sampler might collect (all of which differ from each other). Development and usage of more precise terminology could be helpful. No wonder our sampling technology remains so imprecise…

Specific Comments

P 2-1, line 11: Change "their" to "particle", or add "particles" after "Pb" in line 10.

P 2-2, lines 13,14: It might be helpful to provide a few examples here of the recent or pending Pb emissions reductions, or at least a pointer to Appendix 2B.

P 2-3, lines 13 and generally in this paragraph: Since you have previously emphasized the considerable emissions reductions since the 2008 NEI, why not use the past tense consistently (as in the last sentence of this paragraph)., or "…largest source sector emitting Pb into the atmosphere in 2008 was aviation gasoline…", etc.

P 2-3, line 14: A minor point, but combining mining and metal working into a single category seems a bit odd, and makes for an awkward following sentence, in which fuel combustion is identified as the second largest source category. I wonder if you might instead say something like "Following avgas, which accounted for almost 60% of 2008 Pb emissions, the general metal working and mining, fuel combustion and miscellaneous source categories each contributed 10% to 15% of the 2008 total."

P 2-5, line 13: Would it be possible to provide some indication of how large these pending emissions reductions will be?

P 2-6, lines 15-28: This separate CAA Section 231 review process is interesting and unusual, and would seem to emphasize the importance of the recently initiated airport Pb monitoring. If any exceedances were observed in that monitoring (and/or given the results of the recent Miranda et al. (2011) study), it would seem impossible for EPA to conclude that avgas could not be reasonably anticipated to endanger

public health. Hopefully it will be possible for EPA to report any available results from the recent airport monitoring in a subsequent PAD.

Miranda, M.L., R. Anthopolos, and D. Hastings (2011) A Geospatial Analysis of the Effects of Aviation Gasoline on Childhood Blood Lead Levels, Environmental Health Perspectives 119: # 10, 1513-1516.

P 2-7: lines 3-8: Could you provide a quantitative indication of the reduction (in tons or %) of NASCAR Pb emissions that have resulted from switching to unleaded fuels in the "major" race series? Is there some schedule for elimination of Pb fuels for the remaining "minor" race series?

P 2-7, lines 21 and 28: Can you provide averaging times for these concentrations?

P 2-7, line 33: You could add "historical" before "sources".

P 2-11: There seems to be a slight discrepancy (airport monitoring sites in TX) between the airport monitors indicated in Figure 2-2 and in Figure 2.4. Remind me why airport monitoring is not required at airports emitting > 1 ton?

P 2-12, line 15: Seeing the words "accessible" and "AQS" in the same sentence always brings a smile.

P 2-13, line 20: Has any such additional monitoring been required by the Regional Administrators?

P 2-16, lines 1-3: But presumably some airport sites were operational on or before 12/27/11 and have now collected a year – or at least multiple 3-month periods – of data, which would be of great interest to see in the next PAD.

P 2-16, Figure 2-4: As noted previously, the airport monitor in eastern TX in Fig. 2-4 is not indicated in Fig. 2-2, and a northern TX airport monitor in Fig 2-2 is not indicated in Fig. 2-4.

P 2-18, line 3: You could add "currently" before "quantified" since IMPROVE Pb analysis was conducted by PIXE prior to 6/1/92.

P 2-18, lines 4-5: The VIEWS reference is currently functional. However VIEWS is no longer funded or updated (except for the IMPROVE database). To assure future functionality, you could change "VIEWS website" and link to "FED website (http://views.cira.colostate.edu/fed/)".

P 2-18, line 5: You could add "currently" before "operated" since IMPROVE did not operate on a 1-in-3 day schedule prior to 2000.

P 2-18, lines 7-13: To fix several small inaccuracies, I suggest replacing these 3 sentences with: "The original IMPROVE network began sampling in 1988, with 36 monitors located in or near "Class I" federal areas (including National Parks and Wilderness Areas, which are afforded special visibility

protection under the Clean Air Act). The network underwent major expansions in in the early 1990s and 2000s, and currently includes 110 sites located in or near Class I visibility areas, virtually all of these being rural. Approximately 60 additional "IMPROVE protocol" sites at various urban and rural locations, requested and funded by various parties, have also been included as part of the IMPROVE network (Figure 2-6)."

P 2-19, line 17: As noted in comments on the 3rd draft ISA, I think the term "TSP" is vaguely defined, and used to mean many different things. In this case an "alternative TSP" sampler would not collect the same TSP as the current "Pb-TSP" FRM sampler. If it did there would be no need for it. To clarify the intended meaning, I suggest adding a text box with wording something like: TSP is an acronym for Total Suspended Particles, an hypothetical and un-measurable concept. In this document, we use the term TSP to mean "particles with the size characteristics of those collected by the high volume (Hi Vol) TSP sampler" and Pb-TSP to mean "Pb in particles collected by the Hi Vol TSP sampler". When referring to alternative existing or future samplers with an upper 50% particle cut size larger than 10 microns, but not identical to the Hi Vol TSP sampler, we use the term "TSP" in quotes.
P 2-20, line 7, or elsewhere: This might be an appropriate place to add discussion similar to that recently added to the ISA suggesting that there is some convergence between the practical limits on largest particle cut sizes for size-selective sample technologies and the upper size limits for spatially representative sampling of "airborne" particles that remain suspended for more than a few seconds. For example on page 3-67 of the ISA:

> The relevant particle size distribution for ambient sampling is smaller than the size distribution of the settled dust. Particles larger than about 20 μm are generally considered too large to be transported for more than a few seconds under typical conditions… It follows that 15 to 20 μm may be a practical limit for both good sampling data quality and representative sampling in a limited area.

P 2-22, lines 18-21 and 32-33: Hopefully some of this new data can be presented in the next PAD. While 3 years of data may be needed to develop complete design values for the new monitors, exceedances of the NAAQS could be observed with as few as 3 months of data – and would be informative to see as (or if) they occur.

P 2-24, Figure 2-8: Use of a lower scale (max of 1 μg/m3) would help, if feasible.

P 2-28, lines 6, 7, and Figures 2-11 to 2-13: Could "previous source-oriented sites" be defined? Assuming this means "sites near sources which have shut down", the implication is that this second highest concentration category (where it appears some sites are approaching the NAAQS) would seem to be heavily influenced by fugitive emissions of historically deposited Pb. Or is it possible this category includes Pb sources that have changed operations or controlled emissions below some threshold level? Could the category include sources that were shut down during the 2009-2011 period?

Assuming this category does represent sites where former Pb sources have shut down – and that therefore resuspension of historically deposited Pb is a likely cause of the relatively high concentrations

– it could be informative to report any observed changes over time for sites in this category. It would be important to know if the availability of historically deposited Pb remains constant or diminishes over time.

P 2-28, line 9: Switch "additional" and "indicate".

P 2-28, line 15: Change "Pb" to "Pb-TSP".

P 3-34, line 1: Delete the "0" before "air".

P 3-34, line 2: Change "at" to "near".

P 3-34, line 5: Maybe change "arises" to "originates" to make it clear you're not necessarily talking about dust suspended in the air.

P 3-35, line 1: I must be missing something, but can't understand how controls could reduce ambient concentrations by 75%, but only reduce outdoor dust concentrations and loading rate by 50% - unless maybe dust concentration and loading rate were "measured" by methods that included larger particles (from resuspension of historical Pb deposits) than the ambient air sampling measured.

P 3-36. Line 4: Add "Pb" before "occurring".

P 2-36, line 9: You could add "spatial patterns and" before "documented reductions".

P 2-37, lines 5-27: This is a nice summary, but the little bit of discussion of rates of soil Pb decline as a function of distance from sources like roadways or smelters reminds me that the general topic of Pb gradients (soil, dust, or ambient air concentration) near sources, is not much discussed in the PAD or ISA – but could be useful in terms of exposure assessments, monitor siting, etc. This is also a subject area where some modeling – evaluating concentration and deposition patterns of different particle sizes – could be informative. Maybe next review cycle…

P 2-38, line 12: Can you report how far from the road this "greater distance" was?

Dr. Michael Rabinowitz

Comments on Executive Summary and Chapter 1 (Introduction)

Does the Panel find the introductory and background material, including that pertaining to previous reviews of the Pb standard and the scope of the current review to be appropriately characterized and clearly communicated?

Yes, this text adequately provides the reader with a clear, stand-alone basis to make the decision to retain or revise the current standard. The regulatory background material and the review of the lead pathways in Chapter 1 are satisfactory and sufficient.

Some small additional comments:

On page ES-1 line 25, why not add for emphasis ...This approach was taken to aid in the decision to retain or revise the current standards.

line 31 I concur that retaining the current air standard makes sense, because air lead is not the problem now. Even if we were to move the standard to zero, the response in blood lead levels would be very small, given the other sources of lead exposure.

In Chapter 2 page 2-8 line 22 perhaps add....and these are expected to decrease further with the passage of time.

Dr. Ian von Lindern

Comments on the Introduction (Chapter 1)

This chapter provides context for the review, including the background of past reviews, as well as the scope for the current review. This includes discussion of fate and multimedia pathways of ambient air Pb and other nonair sources of Pb in the environment.

Does the Panel find the introductory and background material, including that pertaining to previous reviews of the Pb standard and the scope of the current review to be appropriately characterized and clearly communicated?

The Introduction provides a clear and concise description of the new Integrated Science Assessment/Risk and Exposure Assessment/Policy Assessment (ISA/REA/PA) process; providing the purpose, background, history, and scope of the review and summary of the document's organization and structure. It is well written and does avoid excessive jargon, so as to be readable and understandable to a general audience.

However, I believe it overdoes the conclusion that no information justifying reconsideration of the NAAQS has accumulated in the last five years, without caveats to convey the level of uncertainty and lack of information in some areas important to consider in the formulation of US lead regulatory policy.

PURPOSE AND SCOPE: The PA does indicate one purpose is to "bridge the gap" between the scientific assessments in the ISA and REA, but a concise description and purpose and scope of the ISA and REA would be helpful. With regard to purpose, my understanding in reading the PA, is that analysis and synthesis are limited to the question as to whether any information has accumulated in the previous 5 years that would prompt reconsideration of the primary and secondary NAAQS; and that, in turn, is limited to indicator, averaging time, form and level.

The general conclusion is that no new information has surfaced through the ISA process that would prompt reconsideration of the indicator, averaging time, form and level. I would generally agree with that conclusion.

However, this conclusion should be conveyed with an assessment of the adequacy of the old information. With respect to health effects, large volumes of new information have come forward to supplement an already rich database. However, for other areas there are significant unknowns and uncertainties associated with the lack of information available for the last review. Those inadequacies and uncertainties should be conveyed to policy makers. A finding that no new data have come forward to assist in reviewing the previous decision based on a paucity of information - sends a different message to policy evaluators, than stating that the new studies don't refute the analysis of the existing database.

With regard to scope, the PA uses the term to accentuate that lead is a multimedia contaminant and the scope of the document goes beyond air. The ISA and REA extend to other media that are impacted by or impact air lead, and project and integrate the effect of lead exposures from other media on human and ecological receptors. This is appropriate and necessary to effectively evaluate the role and impact of air lead regulation and is accomplished in the context of the other media. Apparently, this is in contrast to other priority pollutants as the PA notes.

However, with respect to subject area and geography, the ISA and PA are limited in scope, both in contrast to the former CD/ Staff Paper process; and with respect to the potential impacts of policy decisions to other components of the environment and beyond the US. These limitations are not conveyed in the PA.

With regard to the ISA, it is not clear in the PA that the ISA is limited only to exposures and data sources considered currently relevant to the US population. And that the significance of new studies is assessed only as to how these relate to conclusions drawn in the past review; and then only to studies in the peer reviewed literature. This has resulted in an ISA that is more than 70% dedicated to toxicology, health effects, bio-kinetics, and causal determinations. These are areas that were data rich in the last review, and continue to produce volumes of new peer reviewed information. In contrast, in areas where the least is known and EPA relies on past findings, uncertainty is becoming greater as the existing information becomes outdated; and some areas important to policy determinations have been eliminated from the review and no information is assessed or conveyed.

The areas of great uncertainty include any consideration of information relative to the production, use, and disposition of lead in the US. The last CD noted that lead use in the US by 2006 was nearing the record levels observed during the tetra-ethyl lead gasoline-additive years. Demand for lead for in batteries and electronics is ever increasing. Lead prices have been at record highs despite the global recession. Where the previous CD contained and acknowledged inadequate data on production, use, and disposition of lead in the US – the ISA doesn't mention it, not even as background discussion.

With regard to the REA, the purpose is not described in the PA; but there is an indication that both the staff and CASAC felt a new REA was not warranted. However, the PA fails to note that the 2006-8 REA was less than ideal. The 2006-8 REA was based on modeling exercises; that necessarily had high levels of uncertainty, due to the paucity of production, monitoring and emissions data. As no potentially useful new model input data were identified in the staff literature search in 2010-11, attempting a new REA would have been superfluous. The policy-makers and evaluators should be informed of this lack of data, levels of uncertainty, and decreasing confidence that the REA is reflective of current conditions. Failure to distinguish between no data and supportive data in these decisions could perpetuate the use of these outdated analyses 5, 10, 15 etc. years in future reviews.

In the previous ISA Draft review, I offered comments regarding the change in procedures from developing CDs and Staff Papers to the current ISA/REA/PA. My opinion was, and remains, that this results in insular and less comprehensive review process. In that regard, the historic discussion fails to note that previous reviews were not so limited, and that EPA policy makers and policy critics were

provided with scientifically vetted information regarding the role of lead in US commerce, and data obtained and analyzed from other EPA Offices to use in effecting more comprehensive and holistic policy. A 1990 Staff Paper reviewed by CASAC specifically addressed the consistency and impacts of lead regulation across the EPA and other agencies, resulting in a comprehensive inter-agency policy. No such communication is evident in the new process.

The failure to collect and or assess information relative to the production, use and disposition of lead in US commerce, and the decision to exclude globally representative exposures, precludes the Agency from considering the effects of policy decisions in media other than air, and beyond the boundaries of the US.

<u>As a result, it is inaccurate to indicate that no new information has accrued relevant to the impact of US air lead policy on exposures, health effects, and health and economic damage outside the US. It is more accurate to say that new ISA/PA process excludes consideration of impacts on populations outside the US; that these studies, databases, and other potentially pertinent information was not sought, assessed, nor reported on by the Agency; and that this is a significant change from previous NAAQS reviews.</u>

<u>It would be more comforting to know that information relevant to consideration of the potential harm done overseas by US policy with regard to lead in the air, other media and commerce regulated by the EPA is being vetted, and used somewhere within the Agency to acknowledge or alleviate global suffering.</u>

Historically Emitted Lead is given special consideration in both the ISA and the PA as a residual contaminant in various media, a source of potential emissions, a potential steady-state component of different ecosystems, and a continuing exposure to humans. There is considerable discussion dedicated to the reduction of lead in air and other media in the US over the last four decades.

The analysis notes significant reductions and attributes the decline to various factors. Most of the decline in emissions and ambient air exposures was achieved through the elimination of tetra-ethyl lead gasoline additives. Another major component was substantial decreases in emissions from primary and secondary smelters, and metals processing industries. In the case of gasoline-related emissions, these ceased and other non-lead products were substituted in commerce. This resulted in decreased lead emissions and health and environmental effects in both the US and globally.

In the case of lead production and secondary recovery, however, this production and recovery were exported overseas. The ISA analyses extensively noted the declines in air lead concentrations and past accumulations in soils, sediments and other sinks. However, there is no mention, consideration or assessment of the impact of the “avoided emissions” in their new locales, much of which may be sequestered in repositories in the US, or exported and released in other countries. The ISA and PA did note that these excessive emissions in Asia are detectable in the US, and that contaminated cocoa beans have been observed from Africa, but not at health significant concentrations.

However, in the developing world, these emissions are of considerable significance and, too often, have tragic health consequences. Much of the lead produced in these countries, finds its way to US consumers, is eventually disposed of back to the developing countries; setting up a recycling of exposure. It seems that EPA policy makers should be made aware that these conditions result from the same policy decisions so favorable to US population and the environment, if for no other reason than to convey the findings to other regulatory or legislative functionaries.

Dr. Gail Wasserman

Comments on Chapter 3

How well do sections here map onto conclusions and evidence of ISA?

Sections on both "Public Health Implications and At-Risk Populations" and "Concentration response functions for child IQ decrements" are clearly written, and these sections maps well onto the information presented in the ISA.

Smaller edits

P3-28 L 22 "behavioral [and] physiological factors"
P 3-31 L 19. Differences between black and white individual betoken racial, and not ethnic backgrounds. Differences across subgroups of Hispanics would be "ethnic" differences. The most general way to aggregate these comparisons would be to refer to "different racial or ethnic groups" in L 19.

Dr. Michael Weitzman

Comments on Chapter 3 - Health Effects and Exposure/Risk Information

In my opinion this is an extremely good chapter, and my comments and suggestions are largely editorial or minor in nature.

3-1, line 17 and 18: should the order be changed to "gastrointestinal tract and the respiratory system" as most absorption is via the GI tract although the focus of our work is on ambient air lead?

3-1, line 19-21: This sentence, I believe, is unclear.

3-2, line 19: substitute "one" for "a"

3-2, line 28: I suggest changing "current maternal exposure" to "…to exogenous sources of lead during pregnancy."

3-2, line 31: after "umbilical cord" change wording to "which is representative of newborn blood lead levels"

3-3, line 16: do we know when blood lead levels begin to rise in infancy…I believe it is usually stated that they begin to rise around age 6 months but I am not sure of this.

3-3, line 24: can we cite specific national, i.e. CDC, HUD, EPA, and international health agencies ?

3-4 I have difficulty understanding Figure 3-1

3-5, line 21: I suggest adding "or lead contaminated soil"

3-8, line 14: I suggest adding "their more rapid respiratory rates

3-8, line 27: Mention is made of Table 3-1, I believe the Table should be moved up several pages.

3-14, line 10: Is it possible to estimate the % of blood lead from air by age or to mention that this is not possible to do because of multiple variables, including the intensity of exposure to other sources?

3-14, line 27: I suggest adding "strengthens and extends" conclusions…..

3-16, line 13: do we intentionally mean "is associated with" here or should it be "causes?"

3-21 Under **Measure** some are bolded and others are not bolded—it is unclear to me is this is due to footnote C ***Studies discussed in ISA….***

3-23, line 16: I suggest changing "One exception" to "In addition, one…"

3-27, line 5: I suggest adding after population IQ "and neurocognitive and behavioral"

3-27, line 19: do we mean to say "associated with" or should it be "causes?"

3-29: should we mention very low birth weight, in utero cocaine, heroin, alcohol or tobacco exposure, or head trauma as examples of potentially vulnerable populations, or populations for which we currently have no data regarding the possibility of heightened vulnerability?